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HELLER EHRMAN LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

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LANDSMAN, ROBERT S	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/993,604
Filing Date: November 14, 2001
Appellant(s): ASHKENAZI ET AL.

Barrie Greene
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/28/05 appealing from the Office action mailed 8/11/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. According to Appellants, related application 09/997,542 is still under final rejection, but contains the same issues as the instant application.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed. The request for Change of Inventorship under 37 CFR 1.48(b) filed 3/25/05 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 119-126 and 129-131 under 35 USC 112, first paragraph, lack of enablement has been withdrawn insofar as the claims read on a signal sequence. It would not be undue experimentation for one of ordinary skill in the art to determine the signal sequence of the polypeptide even though this sequence is not precisely disclosed in the specification.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Sen S. Curr. Opin. Oncol.. 12:82-88, 2000

Pennica D, et al. PNAS 95:14717-14722, 1998

Konopka JB et al. PNAS 83:4049-4052, 1986

Haynes PA, et al. Electrophoresis 19:1862-1871, 1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

A. Claims 119-126 and 129-131 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well-established utility. These claims are directed to polypeptides having various sequence homology to SEQ ID NO:326. However, the invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated protein. However, the instant application does not disclose a specific and substantial biological role of this protein or its significance.

However, it is clear from the instant specification that the claimed protein is what is termed an "orphan receptor" in the art. The instant application does not disclose the biological role of the claimed protein or its significance. Appellants disclose in the specification that the receptor is a secreted protein. However, this fact, alone, is insufficient to confer utility to the protein of the present invention. Therefore, the instant claims are drawn to a polynucleotide encoding a protein which has a yet undetermined function or biological significance. There is no actual and specific significance which can be attributed to said protein identified in the specification. For this reason, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real-world" use for said protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

Furthermore, since the protein of the invention is not supported by a specific and substantial asserted utility or a well-established utility, the encoding polynucleotides and chimeric proteins also lack utility.

Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 119-126 and 129-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not

supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

B. Furthermore, even if the claims possessed utility under 35 USC 101, claims 119-123 and 129-131 would still be rejected under 35 USC 112, first paragraph, because the specification, while then being enabling for SEQ ID NO:325 and 326, does not reasonably provide enablement for polypeptides having at least 80%, 85%, 90%, 95% or 99% sequence identity to SEQ ID NO:326, to the protein encoded by ATCC No. 203129, for the extracellular domain thereof, or for fusion proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There is no functional limitation in the claims. The claims encompass an unreasonable number of inoperative polypeptides, or polynucleotides which encode these polypeptides, which the skilled artisan would not know how to use.

There are no working examples of polynucleotides or polypeptides less than 100% identical to SEQ ID NO:325 or 326, or the mature form thereof (i.e. lacking its signal peptide). The skilled artisan would not know how to use non-identical polypeptides on the basis of teachings in the prior art or specification unless they possessed a specific function disclosed in the instant specification, in which there is none. While the specification generally describes homologous proteins, Appellants still have not taught to which family of proteins the protein of the present invention belongs. The specification does not provide guidance for using polynucleotides encoding polypeptides related to (*i.e.,* 80%-99% identity) but not identical to SEQ ID NO:325 or 326 which do not have any specific, known function. The claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of proteases and lack of knowledge about function(s) of encompassed polypeptides structurally related to SEQ ID NO:325, the lack of direction or guidance for using polypeptides that are not identical to SEQ ID NO:326, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 119-123 and 129-131 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides having at least 80%, 85%, 90%, 95% or 99% sequence identity with SEQ ID NO:326, and fusion proteins thereof. The claims do not require that the polypeptide of the present invention possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:326, or encoded by SEQ ID NO:325, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear

that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

A. Claims 119-126 and 129-131 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al. (WO 99/63088). The claims recite an isolated polypeptide at least 80% identical to SEQ ID NO:326 as well as polynucleotides encoding this protein, extracellular domains and chimeric polypeptides. Baker et al. teach a protein which is 100% identical to SEQ ID NO:326 of the present invention (Sequence Comparison). This protein would encompass all of the claimed variants of that of the present invention. Baker also teach chimeric peptides (page 350, line 15).

(10) Response to Argument

Claim Rejections - 35 USC § 101

Appellants begin their arguments by reciting numerous examples of case law. The Examiner takes no issue with the case law.

Appellants argue in the Brief that Example 170 of the specification discloses that the gene encoding PRO1281 showed significant amplification, ranging from 2.099 fold to 2.219-fold in different colon primary tumors. Therefore, such a gene is useful as a marker for the diagnosis of colon cancer, and for monitoring cancer development and/or for measuring the efficacy of cancer therapy. Appellants also argue that the Declaration by Dr. Goddard supports the assertion that the gene is a suitable marker for the diagnosis of cancer.

These arguments have been considered, but are not deemed persuasive. First, it is pointed out that, respectfully, though Appellants state in the Brief that the results are "significant" there is no statistical analysis disclosed, nor is any formula disclosed showing how the data was analyzed in order to determine the significance of the amplification. Even if, as argued by Appellants with regard to the Goddard Declaration (see page 13 of the Brief), this 2-fold amplification was significant, again, this does not provide any significance to the encoded protein. However, it is noted that the Goddard Declaration states that:

> It is further my considered scientific opinion that an at least 2-fold increase in gene copy number in a tumor tissue sample relative to a normal i.e. non-tumor) sample is significant and useful in that the detected increase in gene copy number...

Therefore, it can be seen that this "significance" is based on opinion, not fact. In assessing the weight to be given expert testimony, the Examiner may properly consider, among other things, 1) the nature of the fact sought to be established, 2) the strength of any opposing evidence, 3) the interest of the

expert in the outcome of the case, and 4) the presence or absence of factual support for the expert's opinion. See Ex parte Simpson, 61 USPQ2d 1009 (BPAI 2001), Cf. Redac Int'l. Ltd. v. Lotus Development Corp., 81 F.3d 1576, 38 USPQ2d 1665 (Fed. Cir. 1996), Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 948 F.2d 1182, 25 USPQ2d 1561, (Fed. Cir. 1993). Regarding the interest of the expert in the outcome of the case, it is noted that Dr. Goddard is employed by the assignee and is an inventor in this application. Furthermore, The Declaration of Dr. Goddard does not teach the level of reproducibility or the level of reliability of the results.

Appellants argue that the Sen et al. reference, as with the Goddard Declaration, supports Appellants' assertion that the gene of the invention possesses utility. This argument has also been considered, but is not deemed persuasive. Appellants are attempting to provide utility to the claimed protein based on information about the encoding DNA (gene). However, the fact that the gene may or may not have a utility does not necessarily confer a utility to the encoded protein. This issue has been discussed throughout prosecution of this application. The fact that Appellants used the well-known TAQMAN PCR assay does not persuade the Examiner since this assay is focused on DNA and does not relate to, nor provide any utility for any protein encoded by that amplified DNA.

Appellants argue that "it is not a legal requirement to establish a necessary correlation between an increase in the copy number of the DNA and protein expression levels that would correlate to the disease state or that it is imperative to find evidence that DNA amplification is "necessarily" or "always" associated with overexpression of the gene product. Appellants respectfully submit that when the proper evidentiary standard is applied, a correlation must be acknowledged." Based on this, Appellants argue that none of the references cited by the Examiner (Pennica et al , Konopka et al. and Haynes et al.) supports a lack of utility.

Applicants argue that Pennica do not teach any correlation to increased genes in general, only specifically for the WISP family. What can be gathered from Pennica, in the view of the Examiner, is that, based on the fact that one gene increased in cancer and one did not, that there is only a 50% chance of a gene increasing in a particular cancer. To further add to the unpredictability of gene overexpression in tumors, Applicants argue that Pennica teaches that this overexpression was seen in only 84% of tumors examined. Therefore, given the fact that there is only a 50% chance of finding a gene which may be overexpressed in tumors and that this gene is not even overexpressed on every occasion (84%), it seems difficult to predict that a gene will be overexpressed. In fact, in considering the information of Pennica, it seems more likely than not that a gene will *not* be overexpressed.

Applicants further argue that the Examiner's citing of Konopka was inappropriate since Konopka only teach the *abl* gene. This argument has been considered, but is not deemed persuasive. In fact, Konopka supports the Examiner's position that protein levels cannot be predicted from gene expression. This can be seen in Applicants' quotation from Konopka which states "Konopka et al. actually state that protein expression is not related to amplification of the abl gene but to variation in the level of bcr-abl m'RNA produced from a single Ph template." This, in view of Pennica, make a strong argument about predicting protein levels from DNA overexpression.

Furthermore, Haynes et al. contradict Applicants assertion that there exists a direct correlation between mRNA levels and the level of expression of the encoded protein. In fact, the literature cautions researchers against drawing conclusions based on small changes in transcript expression levels between normal and cancerous tissues. Although, Appellants argue that there is a well-established correlation in the art that the level of protein is positively correlated to the level of mRNA, as indicated above the polypeptide levels of Haynes et al. cannot be accurately predicted from mRNA levels. Therefore, there is no evidence to support Appellants' assertion that there is a working hypothesis among those skilled in the art is that there is a direct correlation between mRNA levels and protein levels. The Declarations and cited references do not establish a substantial utility for the claimed polypeptide. As stated above, the specification does not provide sufficient guidance to the skilled artisan to diagnose or treat any disease.

Though Haynes do not compare gene expression and protein levels, they do teach transcript levels and state that "correlation is 'not linear' and hence, 'one cannot accurately predict protein levels from mRNA [transcript] levels." Even if, as argued by Applicants, Haynes shows that it is more likely than not that mRNA levels correlate to protein levels, the present invention does not disclose mRNA levels, only DNA levels. Given the fact that Haynes is silent to DNA levels it can be assumed, especially in light of Pennica and Konopka, that DNA levels are not correlated (in general) to protein expression levels. Applicants argue that Omtoft, Pollack and Hyman show a general trend between protein and mRNA levels. Again, however, the present specification is concerned with DNA levels, not mRNA.

What can be concluded from Pennica, Konopka and Haynes as well as Appellants' citation of Hanna and Mornin is that there is not definite clear trend with regard to determining protein overexpression based on gene amplification data. Protein over-expression should be determined on a case-by-case basis.

Appellants further argue that Orntoft et al., Hyman et al., and Pollack et al. (made of record in Appellants' Response filed November 4, 2004) collectively teach that in general gene amplification increases mRNA expression. Appellants further argue that the Declaration of Dr. Paul Polakis (made of

record in Appellants' Response filed November 4, 2004) shows that, in general, there is a correlation between mRNA levels and polypeptide levels and, therefore, supports these three references. Appellants further note that the sale of gene expression chips to measure mRNA levels is a highly successful business. Based on this, Appellants state that the central dogma is that the general rule is that protein levels can be predicted based on DNA/mRNA levels. Appellants submit that, "as evidenced by the Ashkenazi Declaration and the teachings of Hanna and Mornin (both made of record in Appellants' Response filed November 4, 2004), simultaneous testing of gene amplification and gene product over-expression enables more accurate tumor classification, even if the gene-product, the protein, is not over-expressed."

Regarding Ornoft et al., the reference appears to have looked at increased DNA content over large regions of chromosomes and comparing that to mRNA and polypeptide levels from the chromosomal region. Their approach to investigating gene copy number was termed CGH. Ornoft et al. do not appear to look at gene amplification, mRNA levels and polypeptide levels from a single gene at a time. The instant specification reports data regarding cDNA amplification of individual gene, which may or may not be in a chromosomal region, which that is highly amplified. Ornoft et al. concentrated on regions of chromosomes with strong gains of chromosomal material containing clusters of genes (see page 40). This analysis was not done for the protein in the instant specification. That is, it is not clear whether or not PRO1281 is in a gene cluster in a region of a chromosome that is highly amplified. Therefore, the relevance, if any of Ornoft et al. is not clear.

With regard to Polakis, only conclusions are provided in the Declaration and does not provide data such that the Examiner can independently draw conclusions. There is no evidentiary support to Dr. Polakis' statement that it remains a central dogma in molecular biology that increased mRNA levels are predictive of corresponding increased levels of the encoded polypeptide. Although, Dr. Polakis states that it remains a central dogma in molecular biology that increased mRNA levels are predictive of corresponding increased levels of the encoded polypeptide, it is important to note that the instant specification provides no information regarding differential mRNA levels of PRO1281 in tumor samples as contrasted to normal tissue samples or the corresponding protein levels. Only mRNA expression data is presented. Therefore, the declaration is insufficient to overcome the rejection based upon 35 U.S.C. § 101 and 112, first paragraph, since it is limited to a discussion of data regarding the correlation of mRNA levels and polypeptide levels.

With regard to Appellants' argument that use of microarrays provides a utility for the present invention is not persuasive since, first, microarrays involve the use of DNA, not proteins. Second, it is the microarray as a whole which has been useful to the industry, not the individual genes.

It is believed that all pertinent arguments have been addressed.

Claim Rejections - 35 USC § 112, first paragraph - enablement

Appellants argue that the claims recite structural features, namely, 80-99% sequence identity to SEQ ID N0:326, which are common to the genus. The genus of claimed polypeptides is further defined by having a specific functional activity for the encoding nucleic acids, namely, that the encoding nucleic acid is amplified in colon tumors. The specification provides detailed guidance as to how to identify the recited variants of SEQ ID N0:326, including methods for determining percent identity between two amino acid sequences, as well as listings of exemplary and preferred sequence substitutions, as well as detailed protocols for determining whether a gene encoding a variant PRO1281 protein is amplified in colon tumor. Thus one of skill in the art could easily identify whether a variant PRO1281 sequence falls within the parameters of the claimed invention.

These arguments have been considered, but are not deemed persuasive.

Even if one of skilled in the art was able to generate polypeptides that are 80%- 99% identical to SEQ ID NO: 326, it will require undue experimentation to assign the functional limitations to these polypeptides. Although, Appellants have amended the claims to assert that the said polypeptide is overexpressed in colon tumor tissue compared to normal colon tissue there is no way of knowing which, if any, variants or fragments would have the same property of overexpression in the specific tissue. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant that demonstrates an altered expression, one of skilled in the art would not know the expression profile of the variant. Modifications to the protein, e.g., by substitutions or deletions, would often result in deleterious effects to overall activity and effectiveness of the protein.

Furthermore, the disclosure fails to enable such a myriad of the claimed polypeptide molecules that not only vary substantially in length, but also in amino acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of polypeptide molecules. In summary, the lack of guidance presented in the specification regarding which variants of polypeptides of SED ID NO:326 would retain the desired activity, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the absence of

working examples directed to variants and the breath of claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, first paragraph – written description

Appellants note that the claims recite structural features, namely, 80-99% sequence identity to SEQ ID NO:326, which are common to the genus. The genus of claimed polypeptides is further defined by having a specific functional activity for the encoding nucleic acids, namely, that the encoding nucleic acid is amplified in colon tumors. The specification provides detailed guidance as to how to identify the recited variants of SEQ ID NO:326, including methods for determining percent identity between two amino acid sequences, as well as listings of exemplary and preferred sequence substitutions, as well as detailed protocols for determining whether a gene encoding a variant PRO1281 protein is amplified in colon tumor. Thus one of skill in the art could easily identify whether a variant PRO1281 sequence falls within the parameters of the claimed invention. Accordingly, a description of the claimed genus has been achieved by the recitation of both structural and functional characteristics, namely, amplification in colon tumors.

These arguments have been considered, but are not deemed persuasive for the reasons provided above under 35 USC 112, first paragraph, lack of enablement. Applicants' arguments are nearly identical for both 35 USC 112, first paragraph, issues regarding percent identity.

Furthermore, the specification provides a written description of only one protein in the genus (SEQ ID NO:326). No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical amino acid residues which would structurally characterize the genus of proteins claimed; thereby not meeting the written description requirement under 35 USC 112, first paragraph. Thought the specification may describe methods to identify polypeptides at least 80% identical to SEQ ID NO:326 and though the artisan can physically identify polypeptides which are 80% identical to SEQ ID NO:326 and which are overexpressed in colon tumors, Appellants still have not provided adequate written description of a sufficient number of polypeptides in the claimed genus.

Even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed SEQ ID NO:326 polypeptides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The claimed product itself is required. Recitation of the phrase "wherein the polypeptide is amplified in

colon tumors" is not adequate to describe polypeptides having 80-99% homology to SEQ ID NO:326, since there was no reduction to practice to support the claims. Specifically, there is no way of knowing which, if any variants would have the same property of over-expression in colon tissues. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant which is, or is not, over-expressed, one of skilled in the art would not know the expression profile of the variant. The mere sequence alone will not allow one of skilled in the art to predict expression. Appellants made no variant polypeptides, and as recited in the current Written Description Guidelines, Appellants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

It is believed that all pertinent arguments have been addressed.

Claim Rejections - 35 USC § 102

Appellants submit that U.S. provisional application 60/141037 has utility based on the gene amplification assay and further that they have made a proper priority claim to U.S. provisional application 60/141037, filed June 23, 1999. Therefore, Baker et al. is not prior art. However, for the reasons presented above under 35 USC 101, Appellants' arguments are not deemed persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Robert Landsman

Conferees:

Brenda Brumback

Janet Andre

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER